

REMARKS

The Office Action dated September 10, 2010, and the references cited therein, have been considered. Claims 1-8 and 10-26 are presently pending. All claims presently stand rejected.

Applicants have amended the claims to address certain subject-matter/formalities/clarity issues raised in the Office Action. Applicants have removed the "means" terminology, with traverse, to emphasize the intention to broadly claim the invention by the functionality/functions recited in the respective claim elements rather than limit the invention to implementations using a specific algorithm and/or hardware.

Moreover, regarding the prior art-based rejections, Applicants note that the claims were previously amended to distinguish the claimed invention, directed to a controlled movement of a sensor, in a direction transverse to a the sensor's measuring plane, during acquisition of signals that are subsequently used to identify strain in tissue which is thereafter related to either hardness or elasticity of the tissue subjected to varying pressure. **Applicants have further amended each of the independent claims, based on Applicants' disclosure at page 3, lines 2-22, to recite that the transverse movement of the sensor is controlled to provide sufficient correlation between consecutive image frames generated from the signals received by the sensor. This aspect of Applicants' claimed invention is neither disclosed, nor even remotely suggested by the prior art.**

Applicants request favorable reconsideration of the grounds for rejection of the previously pending claims in view of Applicants' further amendments to the claims and remarks addressing the shortcomings of the prior art with regard to particular recited elements of the claimed invention.

Please charge any fee deficiencies to Deposit Account No. 12-1216.

Objection to the Declaration

The Office Action has again maintained its **objection to the Declaration** submitted (and accepted) in 2004. This objection has been maintained notwithstanding the previous apparent acceptance of the fully executed (now objected to) declaration in the Office Action mailed on March 16, 2006. Applicants are aware of the requirements of 37 CFR Section 1.52(c)(1), and note that the handwritten changes to the inventor's residence and citizenship were signed by the inventor (the handwritten corrections to the citizenship and residence of the inventor were on the originally submitted declaration) on the originally executed declaration. Several years have passed since the original documents were signed. However, there is no reason to believe that the changes were made after the signing of the original declaration *on the same sheet of paper* (as required in 37 CFR 1.52(c)(1)). The USPTO previously deemed that the requirement to sign changes was met in the original (previously accepted) declaration submission.

Moreover, Applicants note that, even if the rules for signing handwritten changes are not technically met, discretion can be exercised, when circumstances warrant, to waive the specific technicalities upon which the current objection is based. Applicants note that the subject of the change (e.g., residence, citizenship, address, etc. of an inventor) has absolutely no bearing upon the disclosure or substance of the claimed invention. In contrast to initialing/dating changes to the disclosure (i.e., drawings/written description) of an application, Applicants are unaware of any policy or goal that is achieved by the Office Action's current request to re-execute the *declaration* (due to a handwritten change next to an inventor's signature on the document) – *a submission that was considered proper when it was previously submitted AND accepted by the USPTO in 2004.*

Objection to Drawings

The Office Action, at page 2, objects to the use of "second activating means" in claim 19. Applicants submit that the "second activating means" (now "second activator") is shown in FIG. 1 as the activating means 13 and a signal/control line running from the activating means 13 to the actuator. The activating means 13 includes two distinct functional components – a first activator

for activating data storage and a second activator for activating an actuator to draw the sensor along an imaging path.

Objection to Means Plus Function Elements in Claims 14, 18, and 19 (Office Action pages 3-5)

Notwithstanding Applicants' belief that the original disclosure supports a broad interpretation of each element in question as being any of a wide variety of computer/program control apparatuses, Applicants have amended the claims to remove the "means" designating language to conform with the intended broad interpretation of these elements with regard to how the recited functions/functional components are carried out.

To the extent the Office Action suggests that one skilled in the art would understand the claimed/disclosed invention as covering non-computer implementation of the claimed functionality, one skilled in the art would readily appreciate that it would be impossible for any human to perform any of the functions carried out by the elements in question – which would require thousands of computations per second. Applicants have identified support for the specifically claimed elements herein below.

"Correlation Detector"

The Office Action objects to the term "correlation detection means" in claim 14. In addition to the words of the original claim 14, the "correlation detector" is described in the specification at least in "correlation detection means 16" in FIG. 1 and the associated written description at page 7, lines 8-12. As those skilled in the art would appreciate from the description, the correlation detector is carried out by a programmed computing device to compare data representing two consecutive image frames. When read in conjunction with the description of the (storage) activating means 13 (see, page 7, lines 2-4), the correlation detector is programmed to gate a control signal that activates storage of image data rendered by the described system.

"First Activator"

The Office Action objects to the term "first activating means" in claim 18. In addition to the words of the original claim 18, the "first activator" is described in the specification at least as a portion of the "activating means 13" in FIG. 1 and the associated written description at page 7, lines 2-12. As those skilled in the art would appreciate from the description, the activating means

13 is carried out by a programmed computing device to control the storage of received signal data when certain conditions are detected.

"Second Activator"

The Office Action objects to the term "second activating means" in claim 19. In addition to the words of the original claim 19, the "second activator" is described in the specification at least as a portion of the "activating means 13" in FIG. 1 and the associated written description at page 6, line 19 to page 7, line 2. As those skilled in the art would appreciate from the description, the activating means 13 is carried out by a programmed computing device to control the operation of the actuator (e.g., pullback device) which in turn pulls the imaging sensor through the vessel according to a programmed control scheme (e.g., continuous, stepped, etc.).

Summary of the Rejections

1. Claims 14, 18, 19, 25 and 26 are rejected under 35 U.S.C. §112, paragraph 1 as not being enabled.
2. Claims 14, 18, 19, 25 and 26 are rejected under 35 U.S.C. §112, paragraph 2 as being indefinite.
3. Claims 1-8, 10-12 and 25 are rejected under 35 U.S.C. §112, paragraph 2 as being incomplete for omitting essential steps.
4. Claims 13-24 and 26 are rejected under 35 U.S.C. §112, paragraph 2 as being incomplete for omitting essential elements.
5. Claims 1-8, 10-12, 14, 18, 19 and 22 are rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter.
6. Claims 1-8 and 10-12 are rejected as obvious under 35 U.S.C. §103(a) over Torp et al., US Pat. No. 6,099,471 (Torp) in view of Porat et al., US App. Pub. 2003/0220556 (Porat) and Panescu et al., US Pat. No. 5,848,969 (Panescu).
7. Claims 13, 14, 18 and 21-23 are rejected as obvious under 35 U.S.C. §103(a) over Torp in view of Porat.
8. Claims 15-17, 19, 20 and 24 are rejected as obvious under 35 U.S.C. §103(a) over Torp in view of Porat and Panescu.

9. Claim 25 is rejected as obvious under 35 U.S.C. §103(a) over Torp in view of Porat, Panescu and Johnson et al., *The Probability Density of Spectral Estimates...*, 1999 (Johnson).

10. Claim 26 is rejected as obvious under 35 U.S.C. §103(a) over Torp in view of Porat and Johnson.

Applicants traverse the grounds for each and every rejection for at least the reasons set forth herein below. Applicants address the specific rejections in the order they arise in the Office Action.

1. Rejection of Claims 14, 18, 19, 25 and 26 as not being enabled

Applicants traverse the rejection of **claim 14** as failing to comply with the enablement requirement. The Office Action states that the specification does not disclose the structure of the "correlation detection means." However, in addition to original claim 14, the original application describes the claimed correlation detection means in a system comprising signal acquisition and signal processing apparatuses. See, FIG. 1. The "correlation detection means" is described in the specification at least in "correlation detection means 16" in FIG. 1 and the associated written description at page 7, lines 8-12. As those skilled in the art would appreciate from the description, the correlation detection means is carried out by a programmed computing device to compare two consecutively acquired image data sets. When read in conjunction with the description of the (storage) activating means 13 (see, page 7, lines 2-4), the correlation detection means is programmed to gate a control signal that activates storage of image data rendered by the described system. The Office Action places substantial emphasis on the actual physical structure that carries out the claimed "correlation detection means." However, the Office Action does not state that someone skilled in the art would be unable to practice the claimed invention (e.g., program a general-purpose computer) based upon the disclosure of the original specification. **Moreover, Applicants submit that this rejection is rendered moot by the current amendment to claim 14 to remove the "means" terminology.**

Applicants traverse the rejection of **claim 18** as failing to comply with the enablement requirement. The Office Action states that the specification does not disclose whether the "first activating means" is carried out by "either a software application or a hardware application." Applicants had no intention to limit their invention to a particular implementation in either

application-specific hardware or software executing on a general-purpose processor. Moreover, it is unclear how the subject-matter of claim 18 is not enabled simply because the original specification did not explicitly state whether the function performed by the "first activating means" is carried out by *software* or *hardware*. **Moreover, Applicants submit that this rejection is rendered moot by the current amendment to claim 18 to remove the "means" terminology.**

Applicants traverse the rejection of **claim 19** as failing to comply with the enablement requirement. The Office Action states that the specification does not disclose whether the "second activating means" is carried out by "either a software application or a hardware application." Applicants had no intention to limit their invention to a particular implementation in either application-specific hardware or software executing on a general-purpose processor. Moreover, it is unclear how the subject-matter of claim 19 is not enabled simply because the original specification did not explicitly state whether the function performed by the "second activating means" is carried out by *software* or *hardware*. **Moreover, Applicants submit that this rejection is rendered moot by the current amendment to claim 19 to remove the "means" terminology.**

With regard to the "first" and "second" activators (distinguished in claims 18 and 19), Applicants original specification (in the Background section) referred to the "first" and "second" activating means as "activating means" and "further activating means." See, page 5, lines 14-16. The two distinct functional components of the first/second activating means are depicted in FIG. 1 by two distinct output lines from the activating means 13 to the actuator 12 and the data storage means 15.

Applicants traverse the rejection of **claims 25 and 26** as failing to comply with the enablement requirement. The Office Action states that the "specification appears to imply every known probability function can be used to perform the task of determining the optimum overlap." Applicants' specification generally describes using a probability function to determine an optimum overlap between consecutive signals so as not to exclude any particular one of a variety of available probability functions. See, e.g., Applicants' application, page 3, line 15 to page 4, line 3. Claims 25 and 26 generally call for using a probability function. The Office Action does not identify any particular probability function that would not work, nor does the

Office Action assert that a person skilled in the art would not be able to identify a suitable probability function to carry out the described invention. Therefore, the "enablement" based rejection is improper.

The Office Action, at the end of section 10, states that the application fails to disclose "what signals are being used to determine the optimal overlap, and how the optimal overlap is being used to determine hardness of tissue." With regard to the first part of the quote, Applicants note that the signals are signals of a blood vessel wall (acquired using the sensor depicted in FIG. 1). See, page 4, lines 6-8. The comparison is performed between the signal data from consecutive image sets (slices) of an imaged blood vessel wall. With regard to the second part of the quote, Applicants note that the application discloses the optimal overlap (between consecutive image slices) determines whether two consecutive signals are sufficiently similar to perform a stress/strain analysis. See, Applicants' application, page 2, line 25 to page 3, line 22.

2. The Rejection of Claims 14, 18, 19, 25 and 26 as indefinite

Applicants traverse the rejection of **claims 14, 18 and 19** as being unclear. The Office Action states that it is unclear whether the "correlation detection means" is carried out by a software or hardware application. Applicants note that there is no intention on Applicants' part to limit the claimed invention to either special purpose hardware or alternatively a general-purpose processor with application-specific software. The invention can be carried out by a system with either form of programmed control. Claims 14, 18 and 19 have been amended to make clear that the claimed invention, while clearly performed using a computing device, is not limited to a particular software and/or hardware-based computing device.

Applicants traverse the rejection of **claims 25 and 26** as being unclear. The independent claims describe determining strain of tissue from signals obtained while a sensor is moved while the sensor is moved transversely from a measurement plane. As known from the prior art (described in the background), strain is identified by comparing two image planes to determine the relative changes in form of the cross-sections under differing pressures. The "optimum overlap" relates to the claimed invention with regard to the need to compare two substantially similar consecutive image slices under two different pressures. This aspect of the claimed

invention is explained in a way such that one skilled in the art could carry out the claimed computing functionality, for example, at page 3, lines 2-22.

3. Rejection of Claims 1-8, 10-12 and 25 as being incomplete for omitting essential steps

Applicants traverse the rejection of claims 1-8, 10-12 and 25 as being incomplete. It is well established that a claim need only specify a combination of steps that render a method novel and non-obvious. Determining optimal overlap, while beneficial to rendering good strain computations, is not essential to the operating of the system since non-optimal overlap can be used to render satisfactory strain measurements. The "optimal overlap" aspect of the disclosed embodiment is described a page 3, lines 2-22 of Applicants' specification.

4. Rejection of Claims 13-24 and 26 as being incomplete for omitting essential elements

Applicants traverse the rejection of claims 13-24 and 26 for generally the same reason stated above regarding the objection to "omitted steps."

5. The Rejection of Claims 1-8, 10-12, 14, 18, 19 and 22 as Being Directed To Non-Statutory Subject-Matter

Applicants traverse the rejection of **claims 1-8 and 10-12** as being directed to Non-statutory subject-matter (in view of the Federal Circuit's *Bilski* decision). Applicants note initially that the Supreme Court has relaxed the requirement's for patentability established in the Federal Circuit's *Bilski* decision. The Supreme Court decision requires only that the claimed invention, when viewed as a whole, not be an abstract idea. Applicants note that the present claims would even meet the more restrictive Federal Circuit test under *Bilski*. The presently pending claims at issue recite method steps that could not be performed by a person. No person could carry out the "receiving" step (including sub-steps (a) and (b)). One could not imagine any useful embodiment where a human was left to perform, by hand, the millions of calculations needed to carry out the identifying and relating steps. Moreover, the claimed invention renders an identifiable output (hardness or elasticity of tissue value) as a result of the executed steps from the signals received from the sensor.

Applicants furthermore wish to direct attention to the Federal Circuit's subsequent decision in *Research Corporation Technologies, Inc. v. Microsoft Corporation*, Docket Number 2010-1037, Decided on December 8, 2010. The claimed invention involves a method implemented on a computer for rendering an identifiable output. For at least this reason, the rejection of claims 1-8 and 10-12 should be withdrawn.

Applicants traverse the rejection of **claims 14, 18, 19 and 22** as being directed to non-patentable subject-matter. The claimed invention is an "apparatus" (see, independent claim 13 from which each depends). Each of the identified claim elements represents a component of a programmed apparatus (see, FIG. 1 which clearly identifies an apparatus including the claimed means plus function elements identified by blocks). Moreover, the objectionable "means" language has been removed from the claims. Applicants have amended claim 22 to more specifically recite a structure.

6. Rejection of Claims 1-8 and 10-12 over Torp in view of Porat and Panescu

Applicants traverse the Office Action's rejection of claims 1-8 and 10-12 as obvious over Torp in view of Porat and Panescu. A *prima facie* showing of obviousness requires identification of each recited element of the claimed invention in the cited combination of references. However, for the reasons stated herein, the combined teachings of Torp, Porat and Panescu do not disclose each of the recited claim elements in independent claim 1 (or the rejected dependent claims thereof).

In particular, the combined teachings of Torp, Porat and Panescu neither disclose nor suggest acquiring signals from tissue, that are ultimately used to calculate strain (and thereafter the hardness or elasticity) of the tissue, while the sensor is *controllably* moved in a transverse direction while the tissue is subject to a varying pressure, and wherein the transverse movement of the sensor is specifically controlled to provide sufficient correlation between consecutive image frames generated from the signals received by the sensor. This further refinement of Applicants' claim is based, by way of example, on **Applicants' disclosure at page 3, lines 2-22.**

This aspect of Applicants' claimed invention is neither disclosed, nor even remotely suggested by the prior art.

The submitted amendments to independent claim 1 address the points raised in the Office Action that Panescu discloses transverse movement of a sensor. See, e.g., Panescu, col. 10, line 44 to col. 11, line 12. In particular, while Panescu does indeed disclose transverse movement of a sensor, neither Panescu nor any of the other cited references demonstrate any awareness of the possibility of generating the strain value for tissue subject to varying pressure *from signals sufficiently correlated across consecutive image frames* through the claimed controlled movement of the sensor in the transverse direction.

For at least the reasons stated herein, independent claim 1 and dependent claims 2-8 and 10-12, are patentable over the prior art for at least the reasons set forth herein above as well as the reasons previously provided in Applicants' previous response (incorporated herein by reference). **Moreover, Applicants request that any further rejection of the dependent claims be accompanied by an explicit element-by-element tying of alleged teachings in the prior art (column and line numbers) to specific claim elements in the dependent claims. The current rejection's omnibus approach to rejecting the dependent claims 2-8 and 10-12 provides an unreasonably low level of notice regarding the basis for the current rejections.**

7. Rejection of Claims 13, 14, 18 and 21-23 as obvious over Torp in view of Porat

Applicants traverse the rejection of claims 13, 14, 18 and 21-23 as obvious over Torp in view of Porat. Independent claim 13 is amended to include functionality corresponding to the distinguishing elements discussed herein above with reference to independent claim 1. For at least the reasons set forth herein above regarding the rejection of claim 1, Applicants traverse the present rejection of independent claim 13 as well as each of the dependent claims 14, 18, and 21-23. Applicants note that the dependent claims are patentable over the prior art for at least the reasons set forth herein above as well as the reasons previously provided in Applicants' previous response (incorporated herein by reference). **Applicants note the "omnibus" format used at pages 12-14 of the Office Action to reject these dependent claims and request, in the event**

these claims are not allowed, provision of a proper pairing of the recited claim elements and corresponding teachings in the prior art references.

8. Rejection of Claims 15-17, 19, 20 and 24 as obvious over Torp in view of Porat and Panescu

Applicants traverse the rejection of claims 15-17, 19, 20 and 24 as obvious over Torp in view of Porat and Panescu. Each of these claims depends from independent claim 13 (which is amended to include functionality corresponding to the distinguishing elements discussed herein above with reference to independent claim 1). For at least the reasons set forth herein above regarding the rejection of claims 1 and 13, Applicants traverse the present rejection of each of these dependent claims. Applicants further note that the dependent claims are patentable over the prior art for at least the additional reasons set forth in Applicants' previous response (incorporated herein by reference). **Applicants again note the "omnibus" format used at pages 14 and 15 of the Office Action to reject these dependent claims and request, in the event these claims are not allowed, provision of a proper pairing of the recited claim elements and corresponding teachings in the prior art references.**

9. Rejection of Claim 25 as obvious over Torp in view of Porat, Panescu and Johnson

Applicants also traverse the rejection of dependent claim 25. Applicants agree that Johnson does indeed disclose the general concept of calculating probability (density) functions. However, there is no teaching in any of the prior art references to apply such teachings to the claimed method recited in claim 1. In particular, the combined teachings of Torp, Porat and Panescu suggest creating a longitudinal image based upon a series of images taken at points along a vessel. There is no need to have overlapping signals (image slices) since each of Panescu's, Torp's and/or Porat's slices would be an independently generated image slice. In contrast, overlap is needed in the context of Applicants' claimed invention recited in claims 25 in order to properly calculate strain. Since there is no reason to incorporate Johnson's probability density function into Panescu, Torp and/or Porat, the claimed invention is not rendered obvious by Torp, Porat, Panescu and Johnson's combined teachings. Neither Torp, Panescu nor Porat suggests that the inability to correlate between adjacent data signals prevents accurate determination of their respective output values.

10. Rejection of Claim 26 as obvious over Torp in view of Porat and Johnson

Applicants also traverse the rejection of dependent claim 26. Applicants agree that Johnson does indeed disclose the general concept of calculating probability (density) functions. However, there is no teaching in any of the prior art references to apply such teachings to the claimed apparatus recited in claim 13. In particular, the combined teachings of Torp and Porat suggest the creation of a longitudinal image based upon a series of images taken at points along a vessel. There is no need to have overlapping signals (image slices) since each of Torp's and/or Porat's slices would be an independently generated image slice. In contrast, overlap is needed in the context of Applicants' claimed invention recited in claim 26 in order to properly calculate strain. Since there is no reason to incorporate Johnson's probability density function into Torp and/or Porat, the claimed invention is not rendered obvious by Torp, Porat and Johnson's combined teachings. Neither Torp nor Porat suggests that the inability to correlate between adjacent data signals prevents accurate determination of their respective output values.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



Mark Joy, Reg. No. 35,562
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6731
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: March 10, 2011